

Attorney Docket No.: PTQ-0027  
Inventors: Van Eyk et al.  
Serial No.: 09/115,589  
Filing Date: July 15, 1998  
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This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claims 1-79 (canceled)

Claim 80: (currently amended) A method for assessing skeletal muscle damage in a subject, comprising detecting the presence or absence or measuring the amount of:

(a) a peptide fragment of a myofilament protein; or

(b) a covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or

(ii) two peptide fragments of myofilament proteins,

in a biological sample obtained from a subject being assessed for skeletal muscle damage by incubating the biological sample with an antibody or a functional fragment of an antibody that specifically binds to the:

(a) peptide fragment of a myofilament protein; or

(b) covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or

(ii) two peptide fragments of myofilament proteins,

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under conditions which allow the antibody or functional fragment of the antibody to form a complex with the

(a) peptide fragment of a myofilament protein; or

(b) covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein

and an intact myofilament protein; or

(ii) two peptide fragments of myofilament

proteins,

and detecting or measuring the formed complex,

wherein said peptide fragment of the myofilament protein or

said peptide fragment of the covalent or non-covalent

complex formation consists of:

a skeletal troponin I peptide fragment,

a skeletal myosin light chain 1 peptide fragment,

a skeletal troponin T peptide fragment,

a skeletal troponin C peptide fragment, or

an a skeletal  $\alpha$ -actinin peptide fragment,

and wherein the presence or amount of:

(a) the peptide fragment of the myofilament protein; or

(b) the covalent or non-covalent complex of at least:

(i) the peptide fragment of the myofilament

protein and the intact myofilament protein; or

(ii) two peptide fragments of myofilament

proteins,

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in the biological sample is associated with skeletal muscle damage.

Claim 81: (previously presented) The method of claim 80, wherein the peptide fragment of the myofilament protein or the covalent or non-covalent complex of at least:

(i) a peptide fragment of a myofilament protein and an intact myofilament protein; or

(ii) two peptide fragments of myofilament proteins consists of a covalent complex.

Claim 82: (previously presented) The method of claim 80 wherein the presence of at least two different peptide fragments of myofilament proteins or covalent or non-covalent complexes is detected.

Claim 83: (previously presented) The method of claim 80 wherein the amounts of at least two different peptide fragments of myofilament proteins or covalent or non-covalent complexes are measured and the measured amounts are compared as an indication of the extent of skeletal muscle damage in the subject.

Claim 84: (previously presented) The method of claim 80 wherein the ratio of at least two different peptide

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fragments of myofilament proteins or covalent or non-covalent complexes is assessed as an indication of the extent of skeletal muscle damage in the subject.

Claim 85-86: (canceled)

Claim 87: (previously presented) The method of claim 80, wherein the complex is detected or measured by assaying for the presence of a label.

Claim 88: (previously presented) The method of claim 80, wherein the antibody or functional fragment of the antibody is labeled with an enzyme which is detected by measuring enzymatic activity associated therewith.

Claim 89: (previously presented) The method of claim 88, wherein the enzyme is selected from the group consisting of alkaline phosphatase, horseradish peroxidase, luciferase, beta-galactosidase, lysozyme, glucose-6-phosphate dehydrogenase, lactate dehydrogenase, and urease.

Claim 90: (previously presented) The method of claim 80, wherein the antibody or a functional fragment of an antibody is immobilized on a solid phase.

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Claim 91: (previously presented) The method of claim 90, wherein the solid phase is a plastic surface.

Claim 92: (previously presented) The method of claim 80 wherein the skeletal muscle damage is reversible.

Claim 93: (previously presented) The method of claim 92 wherein the skeletal muscle damage is due to at least one condition selected from the group consisting of hypoxia, hypoxemia, ischemia, fatigue and reperfusion.

Claim 94: (previously presented) The method of claim 80 wherein the skeletal muscle damage is irreversible.

Claim 95: (previously presented) The method of claim 94 wherein the skeletal muscle damage is due to at least one condition selected from the group consisting of hypoxia, hypoxemia, ischemia, and reperfusion.

Claim 96: (previously presented) The method of claim 80 wherein the biological sample is selected from the group consisting of skeletal muscle tissue, a component of skeletal muscle tissue, blood, blood serum and urine.

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Claim 97: (currently amended) A method for assessing skeletal muscle damage in a subject, comprising detecting the presence or absence or measuring amounts of at least two different:

- (a) peptide fragments of a myofilament protein
  - (b) covalent or non-covalent complexes of at least:
    - (i) a peptide fragment of a myofilament protein and an intact myofilament protein; or
    - (ii) two peptide fragments of a myofilament protein,
- in a biological sample obtained from a subject being assessed for muscle damage by incubating the biological sample with an antibody or a functional fragment of an antibody that specifically binds to the:
- (a) peptide fragment of a myofilament protein; or
  - (b) covalent or non-covalent complex of at least:
    - (i) a peptide fragment of a myofilament protein and an intact myofilament protein; or
    - (ii) two peptide fragments of myofilament proteins,
- under conditions which allow the antibody or functional fragment of the antibody to form a complex with the
- (a) peptide fragment of a myofilament protein; or
  - (b) covalent or non-covalent complex of at least:

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(i) a peptide fragment of a myofilament protein  
and an intact myofilament protein; or

(ii) two peptide fragments of myofilament  
proteins,  
and detecting or measuring the formed complex,  
wherein said peptide fragments of the myofilament protein or  
said peptide fragments of the covalent or non-covalent  
complexes consist of:

skeletal troponin I peptide fragments,  
skeletal myosin light chain 1 peptide fragments,  
skeletal troponin T peptide fragments,  
skeletal troponin C peptide fragments, or  
skeletal  $\alpha$ -actinin peptide fragments,

wherein the presence or amount of the:

- (a) peptide fragments of the myofilament protein; or
- (b) covalent or non-covalent complexes of at least:

(i) the peptide fragment of the myofilament  
protein and the intact myofilament protein; or

(ii) two peptide fragments of the myofilament  
protein,

in the biological sample are associated with muscle damage,  
and

wherein the

- (a) peptide fragments of the myofilament protein; or
- (b) covalent or non-covalent complexes of at least:

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(i) the peptide fragment of the myofilament protein and the intact myofilament protein; or  
(ii) two peptide fragments of the myofilament protein,  
are from the same myofilament protein.

Claim 98: (previously presented) The method of claim 97 wherein the ratio of the

(a) peptide fragments of the myofilament protein; or  
(b) covalent or non-covalent complexes of at least:  
(i) the peptide fragment of the myofilament protein and the intact myofilament protein; or  
(ii) two peptide fragments of the myofilament protein,  
from the same myofilament protein is assessed as an indication of the extent of the muscle damage in the subject.

Claim 99: (currently amended) The method of claim 80 wherein the myofilament protein is a slow isoform of skeletal troponin I, skeletal troponin T or skeletal troponin C.

Claim 100: (currently amended) The method of claim 80 wherein the myofilament protein is a fast isoform of



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skeletal troponin I, skeletal troponin T or skeletal  
troponin C.

Claim 101: (currently amended) The method of claim 97  
wherein the myofilament protein is a slow isoform of  
skeletal troponin I, skeletal troponin T or skeletal  
troponin C.

Claim 102: (currently amended) The method of claim 97  
wherein the myofilament protein is a fast isoform of  
skeletal troponin I, skeletal troponin T or skeletal  
troponin C.